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EXAMINER

ASTORINO, M

ART UNIT

PAPER NUMBER

3736

DATE MAILED:

11/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/070,677**

Applicant(s)  
**Aria et al.**

Examiner  
**Michael Astorino**

Group Art Unit  
**3736**



☒ Responsive to communication(s) filed on Jul 29, 1999.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-93 and 113-127 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-93 and 113-127 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

The examiner has taken the amendment filed 7/29/99 into consideration. Including the canceling of claims 94-112 as per applicants request, added claims 121-127. All 35 U.S.C. 112, second paragraph rejections from the first office action are removed as per applicants amendment of claims.

#### *Double Patenting*

The following non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. In re Sarett, 327 F.2d. 1005, 140 USPQ 474 (CCPA 1964); In re Schneller, 397 F.2d. 350, 158 USPQ 210 (CCPA 1968); In re White, 405 F.2d. 904, 160 USPQ 644 (CCPA 1969); In re Thorington, 418 F.@d. 528, 163 USPQ 644 (CCPA 1969);, In re Vogel, 422 F.2d. 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d. 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.@d. 887, 225 USPQ 645 (Fed Cir. 1985); and In re Goodman, 29 USPQ 2d 2010 (Fed Cir 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(b) would overcome an actual or provisional rejection on non-statutory double patenting grounds, provided that the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.78(d).

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Claims 1-93 and 113-127 are provisionally rejected under the judicially created doctrine of double patenting.

The subject matter recited in claims 1-93 and 113-127 of the present application was fully disclosed in US Patent Application 09/034,372. The allowance of the above listed claims would extend the rights to exclude already granted in the patent - that right to exclude covering the invention "comprising ABCX". The transitional phrase comprising does not exclude the presence of elements other than A, B, C, X in the claim. Because of the phrase "comprising" the patent not only provides protection ABCX, but also extends patent coverage to the disclosed combination - ABCXY. Likewise, if allowed, the claim(s) of the present application, because of the phrase "comprising" not only would provide patent protection to the claimed combination ABCY, but also would extend patent coverage to the combination ABCXY, already disclosed and covered by the patent. Thus, the controlling fact is that patent protection for the invention, fully disclosed in and covered by US Patent Application 09/034,372 would be extended by allowance of these claims in the present application.

Furthermore, there is no reason why applicant could not have prosecuted the present claims during prosecution of the US Patent Application 09/034,372.

This is a provisional rejection in that the claims have not in fact been patented.

For a more detailed discussion of this double patenting rejection, see MPEP 804(2), under the heading "Non-obvious type."

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***Information Disclosure Statement***

The information disclosure statement filed 7/23/98 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-30, 32, 40-47, 51, 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. in view of Suni et al. and Silvian.

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In regards to claim 1, Allen et al. discloses a sensor with a plurality of conductive contacts/ working and reference electrodes with an enzyme non-leachably disposed (12-14) coupled to contact pads (16) on a subcutaneously implantable electrochemical glucose sensor. Furthermore Allen et al. discloses glucose sensors that monitor blood glucose levels, serving as alarms and a drug delivery system for insulin as it was needed (column 1, lines 17-27). Allen discloses that the glucose sensors would be connected to a suitable monitoring device, however does not disclose the specifics of the monitoring device. Suni et al. does not disclose a monitoring device but does disclose a telemetry system, using transmitters (6) on housing (1) including biosensors (4) against the skin of a user, a battery (column 2, line 53) within the housing including a wearable item (8) wherein the signals are sent to a monitoring system on the wrist of a user. Suni et al. discloses a transmitter however transmitter that is used is not a rf transmitter, thus the range is compromised. It is the examiner's position that the use of a transmitter as per Suni et al. is common in a biosensor monitoring system and obvious to one in the art. Further Silvian discloses the use of a RF transmitter with a bio-sensor, and further Silvian discloses a system wherein a transmitter (37 and 25) and a receiver (33 and 35) are positioned in a monitoring station and a biosensor housing. The examiner acknowledges the fact the Silvian is used for an implantable device, however it is obvious to one in the art at the time of the invention that the use of the transceiver in the sensor and monitoring station is used to maintain an optimum frequency with a biosensor. In conclusion it would have been obvious to one in the art at the time of the invention to combine the glucose biosensor of Allen et al., with a wearable biosensor with a

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housing that transmits signals as disclosed in Suni et al. and the biosensor transceiver as a communication means with a monitor as disclosed in Silvian to maintain an efficient glucose biosensor with a communication means.

3. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. in view of Suni et al., Silvian, and Hill et al.

Hill et al. discloses a glucose measuring device wherein a thermistor is used for temperature compensation. It would have been obvious to one in the art to combine the invention of Allen et al. in view of Suni et al., Silvian, and Hill et al. to maintain an efficient glucose biosensor with a temperature compensation of data.

4. Claims 33 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. in view of Suni et al., Silvian, and Beaubiah.

In regards to 33 and 48, Beaubiah discloses skin conducting biosensor with an working electrode structure including carbon as a conductive material/additive (column 1, lines 1-15, and column 5, lines 29-38). It would have been obvious to one in the art to combine the invention of Allen et al. in view of Suni et al., Silvian, and Beaubiah to maintain efficient skin contacting glucose biosensor with a communication means.

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5. Claims 52-57, 62-78, 89-93, 113-117, 121, 123, and 125-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. in view of Suni et al., Silvian. and Ward et al.

In regards to claim 1, Allen et al. discloses a sensor with a plurality of conductive contacts/ working and reference electrodes with an enzyme non-leachably disposed (12-14) coupled to contact pads (16) on a subcutaneously implantable electrochemical glucose sensor. Furthermore Allen et al. discloses glucose sensors that monitor blood glucose levels, serving as alarms and a drug delivery system for insulin as it was needed (column 1, lines 17-27). Allen discloses that the glucose sensors would be connected to a suitable monitoring device, however does not disclose the specifics of the monitoring device. Suni et al. does not disclose a monitoring device but does disclose a telemetry system, using transmitters (6) on housing (1) including biosensors (4) against the skin of a user, a battery (column 2, line 53) within the housing including a wearable item (8) wherein the signals are sent to a monitoring system on the wrist of a user. Suni et al. discloses a transmitter however transmitter that is used is not a rf transmitter, thus the range is compromised. It is the examiner's position that the use of a transmitter as per Suni et al. is common in a biosensor monitoring system and obvious to one in the art. Further Silvian discloses the use of a RF transmitter with a bio-sensor, and further Silvian discloses a system wherein a transmitter (37 and 25) and a receiver (33 and 35) are positioned in a monitoring station and a biosensor housing. The examiner acknowledges the fact the Silvian is used for an implantable device, however it is obvious to one in the art at the time of the invention that the use

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of the transceiver in the sensor and monitoring station is used to maintain an optimum frequency with a biosensor. It would have been obvious to one in the art at the time of the invention to combine the glucose biosensor of Allen et al., with a wearable biosensor with a housing that transmits signals as disclosed in Suni et al. and the biosensor transceiver as a communication means with a monitor as disclosed in Silvian to maintain an efficient glucose biosensor with a communication means. Furthermore, Ward et al. discloses a monitoring system for a glucose sensor including a RF transmission means from sensor to a computer monitor with a display (134, 136). The examiner acknowledges the use of the biosensor as an implanted bio-sensor. However the location of the sensor is not relevant to the display of data from a analyte monitoring system. In conclusion it would have been obvious to one in the art to combine the invention of Allen et al. in view of Suni et al., Silvian. and Ward et al. to maintain an efficient glucose biosensor with a data display.

6. Claims 87-88 and 124, are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. in view of Suni et al., Silvian, Ward et al. and Hill et al.

Hill et al. discloses a glucose measuring device wherein a thermistor is used for temperature compensation. It would have been obvious to one in the art to combine the invention of Allen et al. in view of Suni et al., Silvian., Ward et al. and Hill et al. to maintain an efficient glucose biosensor with a temperature compensation of data.

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*Response to Arguments*

Applicant's arguments with respect to claims 1-93 and 113-120 have been considered but are moot in view of the new ground(s) of rejection.

*Allowable Subject Matter*

Claims 34-39, 49-50, 58-61, 118-120, and 127 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*


7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abel et al. ('983), Tierney ('685), Netherly et al. ('184), Epstein et al. ('211), Cobb ('001), and Iliff et al. ('297).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Astorino whose telephone number is (703) 306-9067.



M. Astorino

November 8, 1999

  
CARY O'CONNOR  
SUPERVISORY PATENT EXAMINER  
GROUP 3700